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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/739,451	12/17/2003	Dennis Rowe	03762.016200	9345

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
08/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/739,451	ROWE ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-8,10 and 12-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-8,10 and 12-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/07/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed on 05/20/2008. Upon entering the amendment, the claims 1-4, 6-8, and 12-18 are amended. Accordingly, claims 1-3, 6-8, 10 and 12-18 are pending and presented for examination.

Response to Arguments

2. Applicant's arguments filed on 05/20/2008 have been fully considered but they are not persuasive. The 103(a) rejection of Borkan et al. (US 4,935,243) or Hassan et al. (WO-03/090726) in view of Tindal et al. (US 6,387,400) and Tanner et al. (US 6,340, 473) is maintained and made FINAL.

Claim Rejections - 35 USC § 103

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-3, 6-8, 10 and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkan et al. (US 4,935,243) or Hassan et al. (WO-03/090726) in view of Tindal et al. (US 6,387,400) and Tanner et al. (US 6,340, 473).

Borkan et al. teach a chewable, edible soft gelatin capsule which comprises a shell comprising about 20-45% gelatin; about 17.5-35% plasticizer; about 15-30% water and about 5-25% of a hydrogenated starch hydrolysate effective to render said shell dispersible and soluble in the mouth of the user (see abstract and col. 2, lines 51-58).

The disclosed gelatin include fish gelatin (type A) and bovine gelatin (type B) to obtain a gelatin with the requisite viscosity and bloom strength range from 6-300 (see col. 3 lines 30-45). The disclosed plasticizer includes glycerin (col.5, lines 53-56). The disclosed modified starch includes a hydrogenated starch hydrolysate in a weight percentage of about 5-25% (see col. 5, lines 12-15).

Borkan et al. explain those chewable, edible soft gelatin capsules are beneficial because they are capable of convenient delivery vehicle for a unit dosage of the active ingredients. Soft gelatin capsules allow these users to easily chew and ingest the active ingredients within the capsules in a palatable form.

Hassan et al. teaches a soft chewable capsule. The disclosed chewable capsule includes a gel-forming polymer, a plasticizer, a polymer modifier, and water. The disclosed gel-forming polymer composition comprising different types of gelatins from different sources e.g. acid and lime bone bovine gelatins, skin bovine gelatin and fish gelatin (see abstract and page 4, lines 9-12). The disclosed plasticizer includes sorbitol or glycerol, sorbitol, maltitol, xylitol, and combination thereof (see page 2, lines 26-28).

Hassan et al. explain that chewable soft capsule useful as a dosage delivery system. The soft capsule, exhibits a consistency, texture and other organo-leptic properties found desirable in a chewable capsule.

The Borkan et al. and Hassam et al. reference differs from the instant case only in that it does not disclose some of the excipients claimed, i.e. hydroxypropylated starch. However, use of this excipient was well known in the art at the time the instant application was filed, as evidenced by the Tindal et al. reference.

Tindal et al. teach a process for making soft gelatin capsules comprising a gelatin, a plasticizer, and an anti-adhesion agent (see abstract; col. 3, lines 42-50 and col.5, lines 33-42).

The disclosed gelatin include fish gelatin (col. 3, line 49). The disclosed plasticizer, include glycerin (col. 5, line 38). The disclosed anti-adhesion agents include modified starch like hydroxypropylated starches (col. 3, lines 424-50).

Tindal et al. explain that soft gelatin capsules are beneficial because they are capable of retaining liquid fill material, unlike conventional hard shell capsules.

Tanner et al. teaches compositions for the manufacturing of soft capsules (see abstract).

The disclosed capsule includes plasticizer such as glycerin and sorbitol (see col. 6, lines 28-30). The disclosed modified starch such as hydroxypropylated tapioca starch and pregelatinized starch (see col. 6, lines 40-45). The disclosed capsule includes shell thicknesses varying from about 0.024 to9 0.1778 (see col. 13, lines 18-22).

It would have been prima facie obvious to a person having ordinary skill in the art at the time of the invention to develop a edible, chewable, soft gelatin capsule comprising a gelatin, plasticizer, modified starch and water. When these references are taken together, one would have been motivated to extend Tindal and Tanner's teaching

to add hydroxypropylated starch, which may impart acceptable physical characteristics to the soft gel capsule when in an equilibrium state to maximize therapeutic efficacy. As suggested by cited references, one would have reasonably expected successful addition of secondary excipients (hydroxypropylated starch) because effectiveness, extra benefits (.e. consistency, economical to manufacture and increase patient comfort) and safety are already well proven and are well suggested by the latter references.

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by these references cited.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Applicant's arguments filed on 05/20/2008 have been fully considered but they are not persuasive.

Applicant asserts that Borkan and Hassan reference does not teach or suggest the inclusion of a starch or other water retentive agent in an ungelatinized or crystalline form.

Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 10911 231 USPQ 375 (Fed. Cir. 1986). The Borkan or Hassan reference was relied upon merely to show that some of the claimed excipients were well known in the art at the time the instant application was filed. Borkan, clearly teaches that the presence of hydrogenated starch hydrolysate in required amounts augments the chewable and palatable properties of the shell, as well as assists in its rapid dissolution upon chewing.

Applicant asserts that Tindal reference contains only a passing reference of HPS as one of a number of possible components for the casing or sells material and there is no teaching or suggestion of a particular shell composition suitable for a chewable capsule.

This argument is not persuasive since this reference is combined for its teaching of knowledge in the art of using various anti-adhesion agents such as modified starch like HPS for preparing pharmaceutical compositions for use in soft gel formulations. And a reference is not limited to its working examples, but must be evaluated for what it teaches those of ordinary skill in the art. In re Boe, 355 F. 2d 961, 148 USPQ 507 (CCPA 1966). In re Chapman, 357 F. 2d 418 USPQ 711 (CCPA 1966).

Applicant further asserts that Tanner reference does not teach the use of gelatin and Tanner teaches away from the present invention.

This argument is not persuasive since this reference is relied upon to show that it is known in the art to use modified starch selected from modified corn starch (hydroxypropylated corn starch and hydroxypropylated acid modified tapioca starch) capable of forming films from which soft capsule shells can be made. And Tanner also teaches that it is well know in the art for manufacturing, traditionally, both soft and hard shell capsules using mammalian gelatin as the material of choice of for producing the capsule envelop.

Conclusion

1. No claims are allowed at this time.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr